

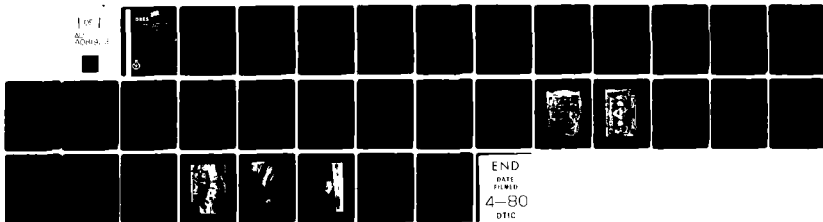
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MICROBIOLOGICAL EVALUATION OF CONTAINMENT ISOLATORS FOR THE CAR--ETC(U)
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FOR THE CARE OF PATIENTS WITH EXOTIC DISEASES (U)

by

A.R. Lejeune, E.E. Howlett, C.G. Watson and
F.W. Stevenson

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ABSTRACT

The microbiological integrity of containment isolators obtained from Vickers Limited Medical Engineering was evaluated using aerosols of T1 coliphage. With the isolators operating as recommended under a slight negative pressure, the protection factor was at least 10^7 and no escape of aerosol was detected with one glove completely removed from a glove port. Decontamination of the interior of the isolator was successful with either formaldehyde vapor or washing with a 10% solution of commercial sodium hypochlorite bleach (Javex).

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INTRODUCTION

The Department of National Defence has agreed to be responsible, through the Surgeon General, for the operation and use of containment isolators manufactured by Vickers Limited Medical Engineering, England and purchased by Health and Welfare Canada. These units are designed to allow transportation and treatment of patients with highly contagious diseases, such as Lassa fever, Marburg virus and Ebola fever, without risking infection of the attending staff.

As part of the overall evaluation of the performance and effectiveness of these units, the Defence Research Establishment Suffield (DRES) was tasked by the Director of Preventive Medicine (DPM) to examine the microbiological aspects of the operation of the containment isolators. Initial tests were conducted by the Defence Research Establishment Ottawa

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(DREO) to determine the integrity of the units using freon gas and a halogen leak detector (Appendix A). This paper reports on the microbiological tests conducted by DRES. These tests include evaluation of the High Efficiency Particle Arrester (HEPA) filters, the ability of the units to retain biological aerosols, and decontamination procedures.

Containment isolators were first developed by Professor R. Trexler of the Royal Veterinary College, London (1) and are manufactured by Vickers Limited Medical Engineering, England. The original concept was the gnotobiological process of raising germ free animals in a positive pressure mode within a filtered closed environment. The containment isolators operate by producing a negative pressure environment within a plastic envelope.

The Containment Bed Isolator (CBI) consists of a large plastic tent with two sections - the bed section and the supply section. When the two sections are joined together, after the patient has been placed within the unit, an airtight tent envelops the patient and all contaminated articles. Negative pressure is maintained within, in order to reduce the leakage in the event of a tear or defect in the plastic. Extracted air is passed through a HEPA filter to remove infectious organisms. The patient is readily accessible to medical attending staff through the wearing of half suits which are welded into the side walls of the envelope. Fresh supplies can be brought in and contaminated articles taken out through the supply port by a system of double bagging, without breaking the microbiological integrity of the system.

The Containment Aircraft Transit Isolator (CATI), considerably smaller in size, was also developed and uses the same principles to transport patients over long distances without contaminating the surrounding environment (2).

A third type of isolator, the Containment Stretcher Isolator, has been developed to move patients over a shorter distance. The isolators can be docked one to another to facilitate the transfer of patients from unit to unit.

Only the CBI and CATI were studied, and are reported upon in this report. A somewhat similar testing procedure has been reported by Hutchinson and collaborators, who demonstrated a high degree of containment in the CBI (3).

Figure 1 shows the CBI, including the bed and supply sections, and Figure 2 the CATI. The tests are reported in two parts: Part I - Biological Aerosol Studies and Part II - Decontamination.

PART I - BIOLOGICAL AEROSOL STUDIES

Materials and Methods

Aerosols of *Escherichia coli* bacteriophage T1 were used to simulate the hazard that might result from patients with highly contagious virus infections. The phage was obtained from the American Type Culture Collection as ATCC 11303-B₁ as was the host strain *E. coli* (ATCC 11303). Stock suspensions of T1 were prepared in double strength nutrient broth with 0.5% NaCl added. The broth contained log phase host cells at a nominal concentration of 10^8 cells/mL. This produced a phage suspension with a concentration of about 10^{10} Plaque Forming Units (PFU) per mL.

Aerosols were generated inside the isolators from a Collison atomizer (4) operated at 26 psi from a cylinder of high pressure nitrogen. An antifoam agent (Dow-Corning Antifoam A) was added to the T1 broth suspensions. The resulting aerosol has very few particles larger than 5 μ m in diameter and is thus essentially all in the respirable particle size range. This then simulates the hazard for respiratory infection. Deposition of these particles on surfaces inside the isolator simulates the same hazard from natural virus aerosols.

Aerosol samples were collected with All Glass Impingers (AGI) (5) and New Brunswick STA slit samplers*. The AGI is capable of accurately sampling high concentrations of microorganisms in aerosols and was used to estimate aerosol concentrations of T1 inside the isolators. The slit

* New Brunswick Scientific Co. Inc., New Brunswick, N.J.

sampler plates become overloaded and impossible to enumerate when aerosol concentrations exceed about 2 particles per liter. This sampler was used to monitor the air space around the isolators in an attempt to collect aerosol particles escaping from inside the isolator during the tests. Slit samplers were operated at each corner of the isolators during each test (see Fig. 2).

The AGI samples were collected and diluted in sterile distilled water (SDW). Aliquots for plate counts were mixed with log phase host cells and the mixture spread evenly on pre-dried tryptose agar plates. Plaques were counted after 24 hours incubation at 37°C. Plates for slit samplers were prepared by seeding a uniform layer of log phase host cell culture on the surface of pre-dried tryptose agar. The plates were used within two hours after seeding and plaques were counted 24 hours after incubation at 37°C.

A number of tests were conducted with both the CATI and the CBI. Tests were conducted with both units in the normal operating mode and with the units under positive pressure. Positive pressure is achieved in the CBI by adjusting the air control valves. In the CATI the air intakes were sealed with plastic covers, the exhaust valve closed. A compressed air line was then passed through one of the cones provided for such purposes and the opening sealed with tape. The CATI was then inflated with compressed air. To test the effect of accidental tearing of the envelope, tests were conducted while operating in the normal mode and cutting one finger at a time from one of the surgical gloves near the head end of the unit and finally removing the glove completely. During this test, the one side of the plastic envelope was pushed in and out each time a glove finger was removed to simulate the air movement in the unit caused by personnel moving around while attending the patient.

An attempt was made to measure pressure differences while operating in the normal negative pressure mode and in the positive pressure tests. The recommended negative pressure of 0.1 inches of water was difficult to maintain and measure accurately even with sensitive meters, and finally visual observation of the curvature of the side walls of the enve-

lope was used as an indicator of adequate pressure differential. Attempts were made to apply a positive pressure of 0.5 inches of water to the units but this appeared to put excessive strain on the plastic envelope and, again, visual observation of bulging of the side walls was used to indicate positive pressure at a somewhat lower level.

In addition, one test was carried out using the CBI with the supply section attached, in the normal negative pressure mode, during which simulated accidental breaking of the seal around the plastic bags used to introduce and remove material from the supply section was carried out.

RESULTS

Preliminary tests indicated that with a small circulating fan operating inside the isolators the aerosol concentration of T1 particles did not measurably increase after 5 minutes of continuous operation of the Collison spray. Using a spray suspension concentration with a nominal count of 10^{10} phage particles/mL an average aerosol concentration of 1.4×10^6 phage particles per liter of air was reached after a 5 minute spray period in the CATI. In the CBI, the aerosol concentration under the same conditions reached 4.2×10^5 phage particles per liter of air. This represents the aerosol challenge used for all testing of each isolator.

When either isolator was operated with a positive pressure inside the plastic envelope all of the slit samplers operating outside became overloaded with aerosol particles containing T1 phage. This was true even for the bed isolator which had previously been tested for leakage with Freon (Appendix A) and all detectable leaks sealed. This overloading indicates an aerosol particle concentration in excess of 2 particles/L in the air sampled by the samplers.

With the isolators operating normally under a slightly negative pressure, a surgical glove had to be completely removed from a glove sleeve to provide an opening sufficiently large to detect escaping aerosol particles using a nearby slit sampler. As well, it was necessary to extend the

glove sleeve outward, fully open, and pump the side wall of the isolator in and out several times before escaping particles could be detected. Performing the same procedure with all five appendages of the glove cut off did not produce a detectable escape of aerosol particles.

Operation of the isolators in the normal mode (slight negative pressure) with the Collison atomizer operating continuously for up to 20 minutes resulted in no collection of aerosol particles in any of the surrounding slit samplers. This indicates an aerosol concentration of less than two particles in 1000 liters of air sampled by each slit sampler. Compared to the concentration of particles inside the isolators this represents an escape of less than 1.4×10^{-7} percent of the aerosol particles from the CATI and less than 4.8×10^{-7} percent from the CBI.

The results also indicated there was no apparent escape of aerosol particles outside the isolator when the proper procedure was used to change plastic bags on the supply section. A large increase in aerosol particles outside the isolator was evident when the plastic bag was completely removed before a new bag was put in place. This action, simulating accidental breach of the supply section integrity, exposed a large diameter port (about 24") in the side of the supply section for several seconds.

PART II - DECONTAMINATION

Methods and Materials

Decontamination of the patient isolator must be considered from several aspects. Some of these are:

- (a) decontamination of the air inside the isolator;
- (b) decontamination of surfaces; and
- (c) the effect of the decontaminant on the isolator materials.

All air entering and leaving the isolator does so through a HEPA filter. Samples of these filters were tested in a wind tunnel by challenging the filters with biological and dioctylphthalate (DOP) aerosols and with

formaldehyde vapor. Air samples were taken from the challenge aerosol before passing through the filter and from the exhaust air after leaving the filter. The filter efficiency is calculated by comparing the concentration of particles in the air before and after filtration. Both the total number of particles in the aerosol and the number of biological particles (spores of *Bacillus subtilis* var. *niger* (BG) or T1 phage) were measured. The total particle count was measured with a Climet Particle Size Analyzer* which separates the particle count into six particle size ranges. Samples for biological assay were taken with AGI samplers (5).

Tests were conducted on the physical effects of various disinfectants on the plastic materials used in the construction of the isolators. Samples of seven different types of plastic used in the isolator and two types of gloves were exposed to a number of disinfectants in sealed museum jars. The disinfectants used were:

- (a) Formaldehyde (37%) solution - vapor and liquid;
- (b) Beta-propiolactone (BPL) - vapor and liquid;
- (c) Ethylene oxide - 12% in Freon;
- (d) 6.25% sodium hypochlorite (Javex) - 10% solution;
- (e) Savlon[†] - 1% solution;
- (f) FI-CLOR[‡] - 0.66% solution;
- (g) Wescodyne[#] - 0.4% solution; and
- (h) Ultra violet irradiation at 170 and 44 microwatts/sq cm.

Samples of plastics were exposed to the disinfectants at room temperature (22°C) for 24 and 48 hours. Visual observations and a crude measurement of tensile strength of the plastics were made before treatment and

* Climet Instruments Co., Sunnyvale, Calif.

† Savlon from Ayerst Laboratories, Montreal, Can.

‡ FI-CLOR is sodium dichloroisocyanurate.

Wescodyne from West Chemical Products Ltd., Montreal, Can.

after 24 and 48 hours of exposure.

Selected plastic samples and disinfectants were used to determine the effectiveness of reducing biological contamination. Samples of plastic representing the heaviest and lightest material used in construction of the isolators were chosen. Four disinfectants were selected on the basis of lack of adverse effects on the plastic samples and ease of application as well as known effectiveness in other situations and applications. These were:

- (a) Formaldehyde vapor - 10 mg/L;
- (b) Ethylene oxide - 12% in Freon;
- (c) 6.25% sodium hypochlorite (Javex) - 10% solution; and
- (d) Savlon - 0.4% solution.

Samples of plastic were dipped in suspensions of 10^6 /mL of BG spores or T1 phage, removed and allowed to air dry. Biological assessment was carried out by immersion of the plastic samples in a tube containing distilled water for BG spores or nutrient broth for T1 phage. After vigorous agitation the liquid was assayed using standard microbiological techniques. Contaminated plastic was exposed to vapor disinfectants in sealed museum jars and samples removed at intervals for assessment. Liquid disinfectants were applied by wiping the contaminated plastic with sponges soaked in disinfectant and allowing the plastic to air dry. Samples were subsequently assayed at intervals for up to 2 hours.

As a result of the preliminary tests attempts were made to decontaminate the CATI with ethylene oxide and formaldehyde vapor, and the CBI with supply section using formaldehyde vapor only. The isolators were contaminated by filling them with aerosols of T1 phage as described in the Part I aerosol tests. Samples were taken by thoroughly scrubbing 25 sq cm areas of the ceiling walls and floor or stretcher with moistened cotton swabs. The swabs were immersed in nutrient broth and thoroughly mixed to release the T1 phage particles. Assessment of the resulting suspension was carried out using accepted assay techniques.

Formaldehyde vapor was introduced by evaporation of solid para-

formaldehyde on a hot plate inside the isolator. The weight of paraformaldehyde used was calculated to provide 10 mg/L of air in the isolator after evaporation. A small fan was used to circulate vapor in the isolator and the main isolator air exchange blower was shut off during the disinfection period. The isolators were air washed using the isolator air exchange system following decontamination.

Ethylene oxide was introduced through a rubber tube from compressed gas cylinders of a mixture of 12% ethylene oxide in Freon. The air exhaust system was operated in an attempt to replace as much of the air in the isolator as possible with the ethylene oxide mixture.

The effectiveness of the air exchange system for clearing aerosol particles from inside the isolator was determined by filling the isolator with aerosol as described previously and operating the system in the negative pressure mode after aerosolization had ceased. Slit samplers were operated continuously to monitor the aerosol concentration.

RESULTS

Neither ethylene oxide nor formaldehyde (vapor and liquid) had any visible effect on the appearance of any of the plastic materials. Liquid BPL caused a noticeable change in the appearance of all plastics but BPL vapor did not. Exposure to even the lowest intensity of UV irradiation caused a slight curling and appearance of stiffening in four of the plastic samples with the most marked effect seen on the material used for the half-suits. The degree of change was proportional to the intensity of irradiation. Sodium hypochlorite and Savlon did not cause any obvious change in the appearance of the plastic samples. FI-CLOR caused a slight discoloration of all the plastics except that used for the sleeves connected to the air filters. There was also a slight roughening of the surface and loss of clarity of the half-suit material and the plastic used for the cones through which tubing, etc. was inserted into the isolator. Wescodyne also produced severe discoloration in the same samples as FI-CLOR but without a change in texture of any samples. Only the FI-CLOR had any effect on the two

glove samples. This was an obvious bleaching and dried appearance. In spite of some visible changes described above, a simple test of tensile strength suggested there was little or no effect resulting from any of the treatments on this physical property of the materials.

The effectiveness of the four disinfectants tested for killing BG spores and T1 phage on samples of the plastic is shown in Table I. The 10% sodium hypochlorite solution is the most effective for short time decontamination. Of the two vapor disinfectants, formaldehyde was better than ethylene oxide. In these tests the formaldehyde concentration was estimated to be about 1 mg/L whereas, in subsequent tests in the isolators, the calculated concentration was 10 mg/L. The results of the tests with ethylene oxide and formaldehyde in the CATI are shown in Table II. Considerable difficulty was experienced in trying to obtain an adequate concentration of ethylene oxide inside the isolator. A concentration of at least 10% is required for effective disinfection but this level is difficult to achieve with a concentration of only 12% as a source. The isolator would have to have most of the air evacuated and replaced with the 12% mixture or else this mixture would have to flow into the isolator as replacement for exhausted air for a long period of time. Also, in the latter case, the exhausted air/ethylene oxide mixture would have to be ducted to the open air outside of buildings. In either case, the procedure would be too cumbersome to be practical. Possibly the CATI could be decontaminated in a large autoclave with ethylene oxide. Care would be required to prevent escape of air from the CATI during placement in the autoclave and while providing an opening to facilitate entry of ethylene oxide into the CATI. As a result, only formaldehyde vapor was used in the decontamination test with the bed isolator. The results of this test are shown in Table III. The formaldehyde vapor at 10 mg/L reduced the number of T1 phage particles below the minimum amount measurable with this technique in less than one hour.

Contaminated air within the isolators is decontaminated before being exhausted by the blower by passing through a high efficiency (HEPA)

filter. Tests were conducted with two representative samples of these filters using BG spores and T1 phage aerosol challenges. The results of these tests are shown in Table IV. Initial tests with the first filter showed considerable passage of BG spores through the filter. Eventually it was discovered that the end pieces of the frame were not securely fastened by the retaining bolts. A few turns of the wing nuts on the retaining bolts resulted in a dramatic improvement in efficiency to the extent that the manufacturer's indicated ratings were exceeded.

Tests were also conducted to determine the effectiveness of the air intake/exhaust system in reducing the concentration of aerosol particles inside the isolators. After filling the isolator with T1 phage aerosol, as described earlier, the exhaust system was operated in the normal manner and the aerosol concentration measured at known intervals. Aerosol depletion was of the order of 50% every five minutes. During this test, slit samplers operated beside the isolators did not collect any aerosol particles indicating that the filter was effectively removing particles from air being exhausted out of the isolator.

DISCUSSION

As is often the case, examination of data from a series of tests suggests more extensive testing that would improve the completeness and reliability of results obtained. In spite of time imposed limitations of testing in this case, it is obvious that both the CBI and CATI reduce the biological hazard to the attending staff very effectively, even with a substantial breach of the integrity of the system. Of course, the nature of the breach as well as the size must be considered. For example, a torn glove would likely not allow escape of aerosol particles, but exposure of the skin of the hand to direct contact with contaminated material is a possibility. Nevertheless, when operated according to the manufacturer's instructions, the isolators are capable of providing an aerosol escape factor in excess of 10^7 , which is well above the factor of 10^5 suggested by the Canadian Medical Research Council for high containment facilities used for recombinant DNA studies (6).

Another difficulty encountered during the aerosol test was the inability to monitor accurately the pressure changes inside the isolator. Visual observation of the concavity of the sidewalls gives only an indication of positive or negative pressure. It would have been contributory to know what pressure changes took place during deliberate breaches of the isolator and while the sidewalls were being pumped in and out.

It appears that decontamination of the isolator is feasible but further testing is required for a more definitive answer. Tests would have to be conducted to determine if the disinfectant effectively penetrated all the passages and crevices in the glove sleeves and half-suits, etc. Also, it would be necessary to know that the disinfectant used was effective against the specific microorganism causing the infection for which any given patient was receiving treatment. Perhaps a combination of disinfectants would be more effective. The answer to these and other questions requires considerably more study and testing. Unless all the unknowns can be effectively defined and answered, it is necessary to consider the alternative of simply autoclaving or incinerating the entire plastic envelope after use with a known infected patient. In the same context, a decision must be made as to whether the HEPA filters will be destroyed after use or attempts will be made to sterilize and re-use these filters. If the isolator and/or filters are to be re-used, a procedure for safe changing of filters must be developed.

In spite of some shortcomings in the tests and results described above, a number of firm conclusions and recommendations can be made.

CONCLUSIONS AND RECOMMENDATIONS

1. When operated according to the manufacturer's instructions, both the CBI and CATI provide a safe and effective microbiological barrier between the patient and personnel providing treatment and therapy.
2. A breach of the integrity of the isolators causing an opening as large as 10 cm in diameter does not appear to defeat the microbiological barrier even during normal treatment activity.

3. Further testing is required to provide more definitive and quantitative results.
4. Decontamination of the isolators appears feasible but, again, more extensive testing would be required for adequate confirmation, particularly with respect to the effectiveness of specific disinfectants on specific microorganisms.
5. Before more effort is expended on more decontamination studies, a decision must be made as whether the plastic envelopes will be re-used or destroyed after known contamination. This applies to the high efficiency (HEPA) filters as well.
6. The air exchange filters exceed performance specifications when properly assembled. Each filter should be tested for leaks before being put into use.
7. A sensitive, rugged pressure gauge would be an extremely useful addition to the isolator. A pressure gauge on the CATI should not be affected by changes in attitude, at least to the extent of attitude changes experienced in aircraft during normal flight operations.
8. With a good pressure gauge, and considering conclusion 2 above, a simple pressure test to confirm the absence of gross leakage would be an adequate safety test of isolator integrity.
9. Use of the supply section to remove or introduce materials and supplies may produce the highest potential hazard from a breach of the integrity of the CBI. Procedures to counteract this or other breaches should be developed and attending staff should ensure that the necessary equipment and material to carry out these procedures are at hand, particularly before starting to use the supply section.

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TABLE I
EFFECTIVENESS OF DISINFECTANTS
Total Number of Spores or Phage Particles on Plastic Sample

| Exposure Time | | Formaldehyde | | Ethylene Oxide | | Na Hypochlorite | | 0.5% Savlon | |
|----------------------|-----------|------------------------|-----------------------|----------------|----------|-----------------|----------|-------------|----------|
| | | Plastic H ₂ | Sample L ₂ | Plastic H | Sample L | Plastic H | Sample L | Plastic H | Sample L |
| Control ¹ | BG Spores | 1640 | 6880 | 1640 | 6880 | 2760 | 13100 | 2760 | 13100 |
| | T1 Phage | 1370 | 1910 | 1370 | 1910 | 9270 | 9015 | 9270 | 9015 |
| 30 Min | BG Spores | 10 | 18000 | 230 | 3570 | 10 | 10 | 180 | 280 |
| | T1 Phage | 60 | 30 | 1800 | 500 | 0 | 0 | 0 | 1090 |
| 60 Min | BG Spores | 60 | 4800 | 50 | 240 | 0 | 0 | 140 | 20 |
| | T1 Phage | 10 | 120 | 2420 | 2770 | 0 | 0 | 110 | 2240 |
| 120 Min | BG Spores | 0 | 30 | 20 | 0 | 10 | 10 | 30 | 140 |
| | T1 Phage | 30 | 250 | 960 | 1900 | 0 | 0 | 30 | 400 |

¹ Control samples suspended in room air 120 min then assayed.

² H = heavy plastic, L = light plastic.

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TABLE II

DISINFECTION OF CATITotal Number of T1 Phage Particles Per Swab

| Post-exposure Time (hrs) | Ethylene Oxide Sample Location | | | Formaldehyde Sample Location | | |
|-----------------------------|-----------------------------------|---------|--------|---------------------------------|---------|--------|
| | Floor | Ceiling | Wall | Floor | Ceiling | Wall |
| before | 85,000 | 10,800 | 16,100 | 66,000 | 33,800 | 13,900 |
| 2 | | | | 0 | 0 | 0 |
| 3 | | | | 0 | 0 | 0 |
| 4 | 139,000 | 53,800 | 12,900 | 0 | 0 | 0 |
| 5 | | | | 0 | 0 | 0 |
| 6.5 | 4,620 | 1,240 | 14,700 | | | |
| 17.5 | 540 | 650 | 380 | | | |
| 27 | 1,090 | 240 | 390 | | | |
| 43 | 260 | 230 | 700 | | | |

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TABLE III

DISINFECTION OF CBI WITH FORMALDEHYDE

Total Number of T1 Phage Particles Per Swab

| Post-exposure Time (hrs) | Location of Sample | | |
|-----------------------------|--------------------|---------|--------|
| | Floor | Ceiling | Wall |
| before | 10,000 | 11,900 | 13,000 |
| 1 | 0 | 0 | 0 |
| 2 | 0 | 0 | 0 |
| 3 | 0 | 0 | 0 |
| 4 | 0 | 0 | 0 |

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TABLE IV

Efficiency of HEPA Filters

| | Exposure Time (min) | Flow Rate (CFM) | Filter No. | Total No. Counted Before Filter | After Filter | Percent Penetration ($\times 10^{-5}$) |
|-------------------|------------------------|-----------------------|---------------|---------------------------------------|-----------------|--|
| BG Spores | 18 | 60 | 1 | 4.22×10^9 | 74 | 0.175 |
| | 23 | 60 | 1 | 4.77×10^9 | 14 | 0.029 |
| | 19 | 60 | 1 | 3.61×10^9 | 15 | 0.042 |
| T1 Phage | 8 | 30 | 1 | 2.13×10^6 | 0 | < 4.69 |
| | 8 | 30 | 1 | 6.34×10^6 | 0 | < 1.58 |
| | 8 | 30 | 2 | 5.90×10^5 | 0 | <17.0 |
| | 8 | 60 | 2 | 3.55×10^5 | 0 | <28.2 |
| Aerosol Particles | | | | | | |
| 0.3 - 0.5 μ m | 20 | 60 | 1 | 7.38×10^6 | 1.2 | 1.63 |
| | 8 | 30 | 1 | 9.50×10^6 | 3.0 | 3.16 |
| | 8 | 30 | 2 | 9.65×10^6 | 3.4 | 3.52 |
| | 8 | 60 | 2 | 1.23×10^7 | 0.8 | 0.68 |
| 0.5 - 1.0 μ m | 20 | 60 | 1 | 1.17×10^7 | 1.3 | 1.07 |
| | 8 | 30 | 1 | 1.27×10^7 | 2.0 | 1.57 |
| | 8 | 30 | 2 | 1.31×10^7 | 1.1 | 0.87 |
| | 8 | 60 | 2 | 1.26×10^7 | 1.3 | 1.06 |
| 1.0 - 3.0 μ m | 20 | 60 | 1 | 2.78×10^6 | 0.2 | 0.72 |
| | 8 | 30 | 1 | 1.06×10^7 | 1.2 | 1.13 |
| | 8 | 30 | 2 | 1.06×10^7 | 1.9 | 1.75 |
| | 8 | 60 | 2 | 5.00×10^6 | 0.5 | 1.00 |

Note: Both filters have rated efficiency of $< 3 \times 10^{-3}\%$ at 50 CFM
and $< 1 \times 10^{-3}\%$ at 25 CFM using NaCl aerosols.

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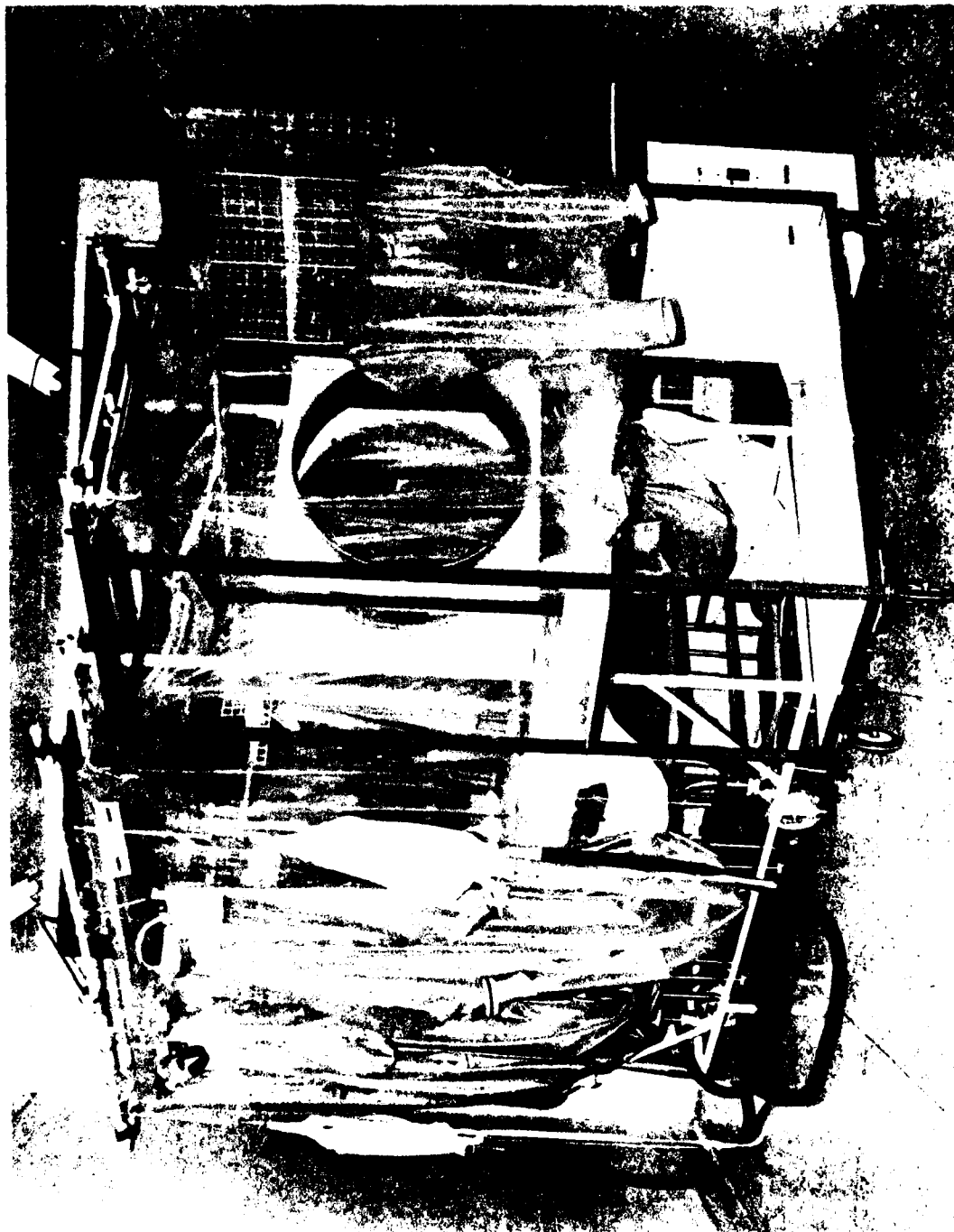


Figure 1: Containment Bed Isolator (CBI) with Supply Section attached.

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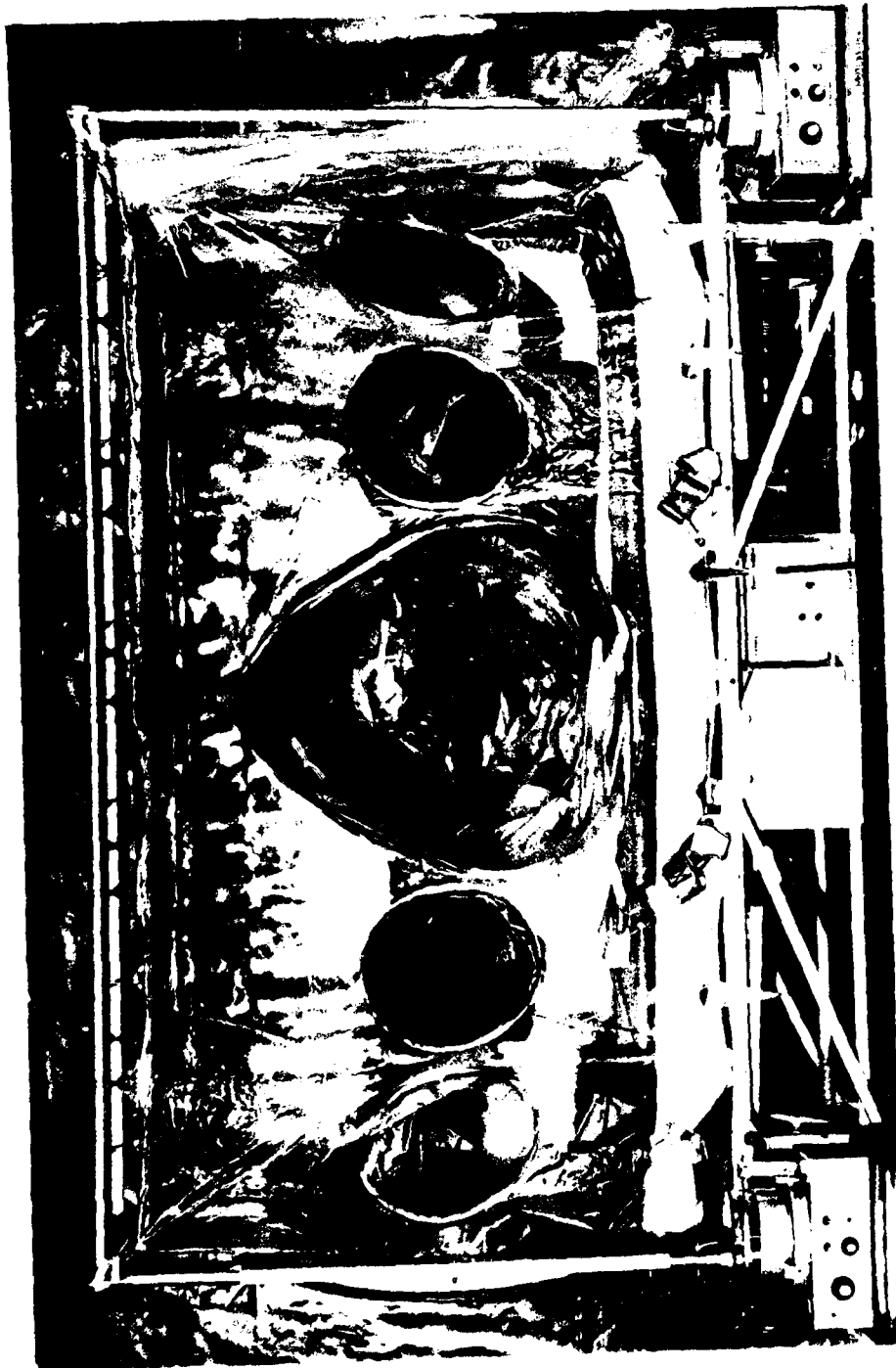


Figure 2: Containment Aircraft Transit Isolators (CATI) and aerosol slit samplers.

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APPENDIX A

LEAK TESTING OF PATIENT ISOLATION UNITS

by

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INTRODUCTION

As part of a task (PCN 16E51) sponsored by DPM at DRES to evaluate the effectiveness of portable patient isolation units, DREO was requested to assess the integrity of the plastic canopies using a tracer gas and appropriate detecting instruments.

This report first gives a brief description of the isolation units followed by an account of the test methods and the results obtained. Finally a procedure for routine testing is recommended.

DESCRIPTION OF THE UNITS

The isolators were manufactured by Vickers Limited Medical Engineering, England. While a variety of isolators are used for a number of different purposes, the units purchased by Canada were intended for transporting and caring for individuals with contagious diseases without danger of infecting the attendants or adjacent areas.

The isolators and how they are used to care for patients, especially the means for introducing and removing food, medication, etc. will not be described in detail. Only sufficient information is given to assist in understanding the leak testing carried out by DREO.

The transit isolator used to transport a patient from one location to another by aircraft, surface conveyance or within a hospital consists of an envelope of transparent polyvinyl chloride supported by an external frame and enclosing a stretcher-type bed. The bed, with patient, is placed in the unit through an oval port at one end. Sleeves on each side are used to move the bed into the proper position and to attend to the needs of the patient while in the isolator. Rubber gloves are attached to rigid plastic cuffs at the ends of the sleeves using "O" rings as elastic bands. The oval port is closed with a plastic sleeve attached to the metal rim of the port with elastics and closed at the outer end by one of a variety of means such as tying, strapping, heat sealing etc. Figure 1 is an

overall view of the transit isolator while undergoing tests at DREO. The stretcher has been removed to facilitate the search for leaks.

The bed isolator is considerably larger and enables a regular hospital bed to be utilized with a patient walk way at one side of the bed. The bed is actually outside of the envelope as is the mattress but there is pocket for the mattress so that bedding can be tucked under it in the normal fashion. Other features include overhead shelves and a bedside table. As on the transit isolator, sleeves are provided for the attendants and there are also half-suits to give better access to the patient.

By connecting the large port of the transit unit to a mating port on the bed isolator, the patient can be transferred from one to the other. After entry of the patient a separate supply isolator can be attached to the large port through which supplies can be introduced and material removed without contaminating the adjacent areas.

Ventilation for the transit isolator is provided by a fan which draws ambient air in through a filter at one end and out the other through another filter to the fan. The fan unit which can be operated at 110V a.c. or by battery can be seen in Figure 1 at the left below the plastic envelope.

The bed isolator is ventilated by two blowers driven by a single motor all enclosed in a box located outside of the envelope. One blower supplies air at up to 15 changes per hour and the other exhausts the air and discharges it into the room, or a hose can be attached to conduct the discharge air elsewhere. Air filters at both the inlet and outlet consist of a roughing filter and an absolute filter giving a maximum penetration of 0.003% of sodium chloride aerosol at 50 cfm.

On the exit air line between the filter and the discharge fan there is a floating-ball-type valve used to regulate the pressure or vacuum inside the isolator. This valve is attached by a chain and levers to the top of the plastic envelope. An increase in internal pressure moves the top of the envelope upward thereby opening the valve to allow the pressure to be reduced. The pressure setting is adjusted by varying the suspension of the ball in the valve or by moving a weight on one of the levers.

Because of its size and because its use might have been required on short notice the bed isolator was tested at National Defence Medical Centre, Ottawa.

EXPERIMENTAL

Apparatus and Materials

1. Leak Detector

The instrument used was a General Electric halogen leak detector, Model H-25 "The Ferret." It is a portable unit with a hand-held probe designed to locate leaks in pressurized systems containing a halogen-compound gas or any system where such a gas can be introduced as a tracer. It incorporates a leak-rate meter which provides an indication of the presence and size of a leak. A selector switch allows a wide range of leak rates to be covered. The instrument has an audible alarm and an alarm lamp in the probe which can be separately adjusted to indicate any leak level thus eliminating the need to observe the meter. With a fluorocarbon refrigerant such as F-12 it can detect leaks from 3×10^{-4} down to 10×10^{-8} std cm³/s. Leak devices which emit known amounts of fluorocarbon gas can be procured to test and calibrate the instrument but these were not used for this task.

The halogen leak tester can be seen in Figure 1 on the shelf at the far end of the transit isolator.

2. Fluorocarbon gases

Properties of several fluorocarbon gases are listed below:

| <u>Code</u> | <u>Formula</u> | <u>mp °C</u> | <u>bp °C</u> |
|-------------|---------------------------------------|--------------|--------------|
| F-22 | CHClF ₂ | | -40 |
| F-12 | CCl ₂ F ₂ | -155 | -30 |
| F-21 | CHCl ₂ F | -135 | 9 |
| F-11 | CCl ₃ F | -111 | 24 |
| F-113 | CCl ₂ F-CClF ₂ | - 35 | 48 |
| F-112 | CCl ₂ F-CCl ₂ F | 24 | 93 |

The compound Freon F-113 was used for these tests because it is a liquid at room temperature which made it easier to inject known amounts into the isolator. Freon F-112 could also be used but it can sometimes be a problem because of its high melting point.

3. Inflation pump

A rotary-vane air pump with a capacity of 1.1 cfm was used to inflate the transit isolating chamber prior to leak testing. A pump with a larger capacity, perhaps 2-4 times this would have been more practical.

For the bed isolating unit, the ventilation blowers were used for inflation.

4. Manometer

An inclined manometer was used to measure both positive and negative pressures in the two units.

A simple curved tube manometer with a range of 8 mm ((Dwyer Instruments Inc. Mark II Model MM-80) was ordered for this work but did not arrive until after the DREO portion of the task was completed. This instrument was transferred to DPM to assist in routine testing of patient isolators.

Procedure Recommended by Manufacturer

The supplier of the isolating units describes a method to assess the integrity of the plastic envelopes after manufacture. The pressure is increased to about 10 mm of water with a separate blower and the blower and exhaust lines are then shut off. If, after 10 minutes, the pressure has dropped by more than 4 mm a large leak is suspected and must be located and repaired. Leaks should be located and repaired until the internal pressure does not drop from 6 mm to less than 4 mm in a period of one hour.

Leak Testing at DREO

To prepare the transit isolator for leak testing at DREO the air line to the blowers was disconnected and the hose from the envelope plugged by a No. 15 rubber stopper.

The air inlet to the filter was sealed with a rubber glove attached with an "O" ring. The plastic sleeve on the entry port was heat sealed to form a large bag. The pump and manometer were connected to the unit through a No. 15 rubber stopper inserted in one of the cuffs in place of a rubber glove.

We experienced considerable difficulty in obtaining a slower rate of pressure decrease than that suggested by the manufacturer. On examination it was found that several of the plastic sleeves had holes at the cuffs as if the cuffs had been rubbed against a hard surface. This could have happened when practising with the unit at NDMC or possibly during shipment from NDMC to DREO. Some of the cuffs had sharp projections along the mold lines that would have worn through the sleeve material very quickly. These holes were patched with plastic tape as shown in Figure 2.

After sealing all the holes and leaks that could be found by visual examination, the unit was charged with freon and surveyed for leaks with the probe of the leak detector. It was found useful to insure the correct operation of the detector by holding the probe near a needle hole located in one of the rubber gloves. This also ensured that the enclosure contained sufficient freon and that it was mixed well enough with the air to appear at the location of the test hole.

With the leak detector a tear was found at the joint between the envelope and one of the heavy plastic lugs used to hold the envelope to the frame. This was sealed with plastic tape as in Figure 3. There were leaks where the plastic "bag" was attached to the entry port with its elastic band. These were corrected by tightly wrapping a length of rubber tubing twice around the metal nozzle and tying the ends.

The bed isolator had a much higher degree of integrity than the transit isolator. The service module, since it could be tested in the same manner as the transit isolator, was removed from the unit. The entry port was sealed with a sleeve which had been closed with a plastic strap used for tying electrical wires together. The sleeve had then been cut close to the tie strap and an effort made to heat seal the ends. This would be an effective sealing method if considerably more tension could be applied to the strap. The unit was pressurized with its own blower system after adjusting the control mechanism to give a positive pressure. This was done by placing a weight on top of the canopy. Although it did not appear to be necessary, the valve on the air supply pipe was closed after shutting off the blowers on attaining the desired pressure. The pressure regulating valve adequately prevented air from flowing out through the exhaust hose.

To mix injected freon with the air inside the enclosure, four small fans of the type used for ventilating electrical apparatus were mounted over the bed and in the space beside the bed. The cord to supply electrical power to the fans was brought through a finger of a rubber glove and the joint sealed with tape.

Trials were made with both units to estimate the maximum hole size that could exist before freon would leak out when they were operated at their normal suction pressure. During these tests the sides of the canopies were moved in and out to simulate the action of an attendant caring for a patient and possibly expelling contaminated air by suddenly increasing the internal pressure. With the probe held $\frac{1}{2}$ -1 inch away, freon was detected from holes larger than $\frac{1}{4}$ inch in diameter. No escape of freon was detected from a sleeve of one of the half suits with the rubber glove removed. However, flow of air to the exit was restricted because the sleeve was partially collapsed under the reduced pressure.

Recommended Test Procedure

1. Install one or more fans to mix the tracer freon gas with the air in the envelope. Mixing is probably not required except for the bed insulator, and even then experience may show that this is not necessary.
2. Visually examine cuffs, attachments at entry ports, etc., seams and other seals for obvious tears, holes or inadequate seals. Make sure all cuffs and sleeves are provided with rubber gloves or other seals. Seal all ports and other openings. On the transit isolator disconnect the air exhaust hose and seal it. Also seal the inlet filter.
3. Connect the manometer through a rubber stopper in a convenient sleeve and for all units but the bed isolator connect the rotary compressor through the same stopper.
4. Pressurize the unit to 6 mm of water or less with the ventilator fans of the bed unit or with the air compressor. Inject liquid F-113 through a septum in a sleeve using 1.0 ml for the bed isolator, 0.2 ml for the transit unit and corresponding amounts for service modules, etc.
5. To verify mixing of the freon in the canopy and operation of the detector, make a needle hole in one of the gloves and insert a short length of 1.0 mm OD (0.5 mm ID) Teflon tubing. The instrument should respond to the freon escaping through the tubing at a setting of C on the sensitivity dial.
6. Survey the plastic canopy and connections to it with the detector probe. As each leak is found repair the plastic or seal the joint.

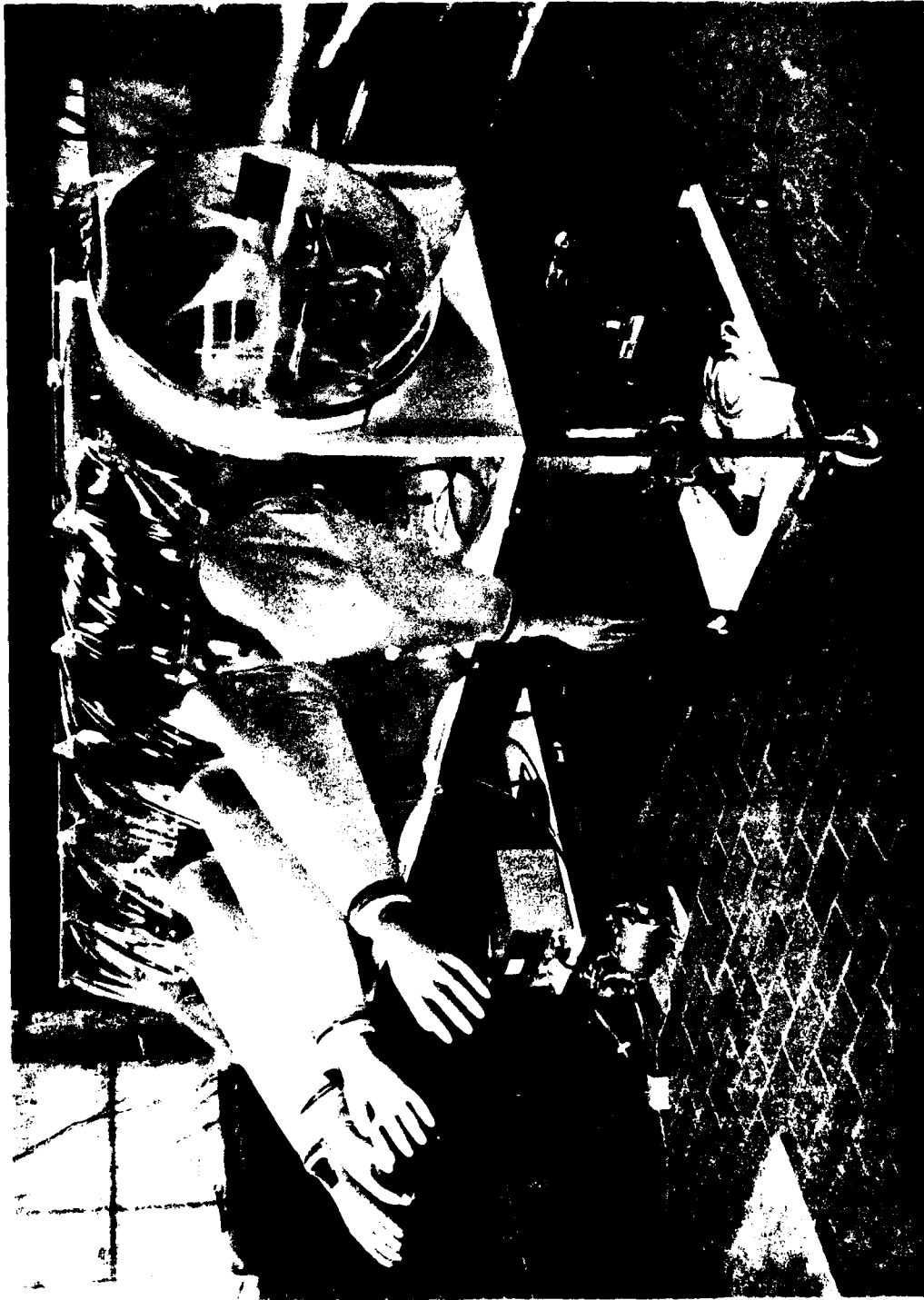


Figure A-1: Overall view of the transit isolator during testing at DREO showing the entry port on the left just above the fan and motor. At the far right are the halogen leak detector and the air compressor used to inflate the canopy.



Figure A-2: Close up of the cuffs and rubber gloves showing plastic tape covering leaks.



Figure A-3: Close up of the tab attached to the plastic canopy so that it can be hooked to the supporting frame. The tape is covering a leak where the tab is sealed to the canopy.

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| 13. ABSTRACT The microbiological integrity of containment isolators obtained from Vickers Limited Medical Engineering was evaluated using aerosols of T1 coliphage. With the isolators operating as recommended under a slight negative pressure, the protection factor was at least 10^7 and no escape of aerosol was detected with one glove completely removed from a glove port. Decontamination of the interior of the isolator was successful with either formaldehyde vapor or washing with a 10% solution of commercial sodium hypochlorite bleach (Javex). (U) | | |

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